Things You Need to Know!

by Virgil H. Simons

We, as prostate cancer patients, survivors, family members and caregivers, are in a period of bounty relative to the number of new drug protocols that have been approved within the last 5 years, which offer hope to those with advanced stage disease of extended life survival.

Yet in the face of the positives, we see forces of negativity that would threaten this progress. Most recently the New York Times questioned the value of the recently approved immunotherapy drug, Provenge, on the basis of cost and the survival data shown. The Prostate Cancer Roundtable, a national group of patient advocate organizations of which The Prostate Net is a member, responded forcefully with a Letter challenging the Times’ assertions. You can read the detail here: http://www.nytimes.com/2011/07/15/opinion/lweb15prostate.html?_r=1&partner=ps

Additionally, the discussions going on, or not depending on your perspective, in Congress regarding the debt ceiling include a plan for $3 billion in cuts to Medicare reimbursement for cancer-fighting drugs and biologics. Due to the financial and administrative burdens that currently exist, community oncology practices already are reducing services and closing their doors across the United States at alarming rates. Additional Medicare cuts will result in a delay of services. The cumulative effect of these cuts is compounded by the fact that chemotherapy agents are reimbursed at artificially low rates under Medicare because manufacturer-to-distributor prompt pay discounts are included in the calculation of average sales price. Congress can protect the interests of

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both the Medicare program and Medicare beneficiaries by promoting evidence based medicine, not through wholesale cuts.

According to the University of Utah Drug Information Service, as reported by ASCO, the number of oncology drug shortages has tripled between January 2006 and December 2010. Last year there were over 211 medications in short supply affecting numerous classes, including chemotherapy drugs, antibiotics and anesthetic drugs. ASCO President, Michael P. Link MD, presented startling statistics that illustrate the growing problem of medications in short supply. “From 1996 to 2003, there was an average of 60 new drug shortages annually. From 2003 until today, there is an average of 150 new shortages each year.” Dr. Link explained how 2011 could be the worst year since the problem has been tracked. “Through the middle of June, there are already 156 new drug shortages. If this trend holds through the rest of the year we must brace ourselves for more than 300 new cases. When it comes to many chemotherapy medications, there are no good alternatives.” Dr. Link outlined the many consequences shortages have on cancer patients and oncology practices including treatment delays, less effective or no work-around therapies, patient anxiety, the time and expense practices waste on finding supply, the adverse effect on ongoing clinical trials and a price markup that increases the cost of care. Many in the oncology community are backing two Congressional bills introduced this year for provisions they contain that are important first steps in addressing this complex issue. The Preserving Access to Life-Saving Medications Act, which was introduced in February by Senators Amy Klobuchar (D-Minn.) and Robert Casey (D-Pa.), contains some of the recommendations from the November 2010 Drug Shortages Summit and H.R. 2245, legislation that would provide the FDA with enhanced authority to require notification from a manufacturer when the manufacturer expects a disruption in their usual supply of drugs introduced in June by Representatives Tom Rooney (R-Fla.) and Diana DeGette (D-Colo.). Policymakers must not prevent patients from being able to benefit from great discoveries in cancer treatment.

The Centers for Disease Control and Prevention (CDC) has reported that some 42 states and the District of Columbia have closed or are working to close $103 billion in shortfalls for the coming fiscal year (FY2012). These gaps are all the more daunting because states’ options for addressing them are fewer and more difficult than in recent years. Temporary aid to states enacted in early 2009 as part of the federal Recovery Act was enormously helpful in allowing states to avert some of the most harmful potential budget cuts in the 2009, 2010 and 2011 fiscal years. But that aid will be largely gone by the end of the June, when FY2011 comes to a close. To date, budget difficulties have led at least 46 states to reduce services for their residents, including some of their most vulnerable families and individuals. Tobacco cessation, pregnancy prevention, and childhood immunization programs are just a few of the programs that are being cut across the country in response to budget cuts at all levels of government. The significant gains that state and territorial health agencies (SHAs) made in the past decade are in jeopardy as agencies are forced to cut critical programs and reduce staffing levels. The result: People whose lives often depend on these services are losing their safety net. The American Recovery and Reinvestment Act (ARRA), enacted in February 2009, includes substantial assistance for states. Most of this money is in the form of increased Medicaid funding: In addition, H.R. 1586 — the August 2010 jobs bill — extended enhanced Medicaid funding for six months through June 2011 and added $10 billion to the State Fiscal Stabilization Fund. But even with this extension federal assistance will end before state budget gaps have fully abated. The Medicaid funds are scheduled to expire in June 2011, the end of the 2011 fiscal year in most states. One way to avert the need for these kinds of cuts, as well as additional tax increases, would be for the federal government to reduce state budget gaps by again extending the Medicaid funds over the period during which state fiscal conditions are expected to still be problematic. But such an extension appears to be a remote possibility. Again, we see potential negative impacts on the health of our society, particularly among those most in need of financial assistance.

Research advances since President Nixon declared “War on Cancer” have enabled many significant advances that have made the treatment of prostate cancer one of the most effective, if detected early, and, even in advanced stages, brought greater survival advantages than were present less than 5 years ago. Yet Congress is moving to cut funding for one of the most effective research programs that we’ve had in place — the Congressionally Directed Medical Research Program (CDMRP) at the Department of Defense’s Prostate Cancer Research Program (DoD PCRP). The research funded by DoD PCRP has led to many dramatic improvements in our nation’s prostate health, from decreases in deaths due to prostate cancer to increased life expectancy for men facing terminal diagnoses. In a recent briefing study from the Prostate Cancer Foundation,
Active Surveillance: Aggressive Watchful Waiting

Watchful Waiting is a term that evokes different responses in different people. To some men, it means an unbearable delay in treating their prostate cancer—“just get it out of there” is a common response. To others, it means avoiding, temporarily or permanently, radical treatments like surgery or radiation cycles with their potential side effects and altered quality of life. For a man with low-risk prostate cancer, there is another form of watching and waiting: Active Surveillance.

Active surveillance includes regularly scheduled check-ups and biopsies, with intervention as needed. According to Cancer Research UK, “Watchful waiting means keeping treatment to control prostate cancer in reserve, because you aren’t having any symptoms. You are having active surveillance if your doctor intends you to have radical treatment to try and cure your prostate cancer if it starts to grow.” Johns Hopkins’ Brady Urological Institute’s webpage describes it this way, “In the past, the term watchful waiting meant no treatment until the development of metastatic disease, at which time androgen ablation (hormonal) therapy was initiated. Today, men who have very low to low risk prostate cancer, and who choose no immediate treatment… are closely monitored with intervention, if necessary, at a time when a cure is still possible.”

As concerns continue in the U.S. about the possible overtreatment of prostate cancer, it appears more men are re-considering a rush to radical therapies. James Mohler, MD, chair of the National Comprehensive Cancer Network, points to the NCI-Canada ‘START’ clinical trial to illustrate the trend. This Phase III trial randomly assigns men with low-risk prostate cancer to either active surveillance or immediate treatment. When they started accruing patients in 2007, most men who refused to join the trial did not want to risk being assigned to active surveillance. “Now most men are declining to participate because they want active surveillance,” said Dr. Mohler.

How patients are monitored continues to evolve and varies depending on the physician or institution. Typical monitoring protocol combines yearly, or twice yearly, exams that include PSA monitoring, Digital Rectal Exam (DRE) and regular, possibly annual, biopsies. All of those tests and exams combine to give a clearer picture of the current state of the prostate cancer. As with all treatment decisions, risks and benefits must be thoroughly considered. For example, repeat biopsies might cause inflammation, infection, or scarring. In addition, the patient’s willingness and ability to participate in regular monitoring and follow-up procedures must be discussed.

Active surveillance provides another treatment option for men with low-risk prostate cancer. Guidelines for different therapies are a place to start, but, in the end, it is critical to note that a cancer attack plan must be formulated for each person. Dr. Julio Pow-Sang, of the Moffitt Cancer Center and Research Institute in Tampa, Florida, summarizes, “We know that intervention is good in selected men and that other men do well without any intervention. Treatment must be individualized.”

One Man’s Active Surveillance on Prostate Cancer

Alan Hiller is a 73 year-old retiree who spent the better part of 47 years in executive sales and marketing for major food corporations and is now a successful consultant.

Hiller was diagnosed with prostate cancer in November 2009. Rather than accept his former urologist’s strong recommendation for either surgery or radiation, he embarked on an educational campaign to learn all he could about prostate cancer and his specific diagnosis.

“Although I experienced fluctuating PSA scores for the prior 10 – 12 years, there was never any hint of cancer until my PSA leveled off at 8.6 and stayed there after an acute bout of prostatitis,” said Mr. Hiller. “After a biopsy) my local urologist at the time recommended either surgery or radiation, and said a decision should be made rather rapidly. However, back in 2005, I (had) read an article written by Dr. Ihor Sawczuk, currently Chief of Urology at Hackensack University Medical Center. In this article, (Sawczuk) put forth his belief that too many men who are diagnosed with prostate cancer have almost a knee-jerk reaction and choose interventional treatment. He believed that “active surveillance” could be a very viable path for those patients who qualified for such treatment…. but only with major emphasis on the word active.” This is a progressive management protocol that goes beyond the old concept of “watchful waiting”, which had no active monitoring component until the patient’s disease had progressed, often into metastatic stages.

“. . . having a very negative outlook regarding the possible side effects of incontinence and impotence, and with Dr. Sawczuk’s article in mind, I decided that I wanted to learn as much as possible about this disease and other treatments if applicable,” he said. After assimilating the input from medical professionals from across the country (including Dr. Sawczuk, Dr. Patrick Walsh of John Hopkins University, Drs. Ritchie, Taplin and Beard of the Dana Farber Cancer Institute, and Dr. Aaron Katz of Columbia University, who heads the holistic center for prostate health) and considering the advice of several physicians and fellow prostate cancer patients, Hiller decided to pursue active surveillance. As of January 31, 2011, his biopsies show no signs of cancer.

In addition to the regular PSA tests, biopsies, and urinalysis that characterize active surveillance, Hiller has chosen to combine them with Katz’s holistic approach, which includes the elimination of certain foods.

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and the addition of other foods, as well as the daily ingestion of over 30 nutritional supplements. He believes this, and his very active exercise regimen, has been the key to his remission. Hiller credits his daughter, Shayna, and wife Charlotte, both certified holistic health coaches, for helping him apply optimal health techniques. He is quick to acknowledge that his newly acquired holistic lifestyle is one that he will follow and respect for the rest of his life.

J.A.: What triggers would spur you to reconsider traditional methods?

Hiller: “Per Dr. Sawczuk, who is monitoring my progress, there are three signs that I should consider for other, more traditional, treatment methods: If PSA levels rise above a 3 or 4, there is an upward trend or if PSA levels double, it’s time for a biopsy.”

(Note: In January 2010, Hiller’s PSA level was 8.6; most recently, the PSA level was 6.4.)

J.A.: How do you deal with the potential anxiety and uncertainty of active surveillance? Many men who have been diagnosed say, “I just want to get the cancer out of there.” What are you doing, from a mental standpoint, to deal with the fact that you have cancer?

Hiller: “This is not my first struggle with cancer. Several years ago, I had two small spots of skin cancer removed and I thought I was safe. When my previous urologist started with, “I’m sorry to tell you…,” I panicked and immediately imagined the worst-case scenario.” Hiller noted that he began experiencing mild to moderate depression, as he considered the possible side effects of prostate cancer treatment (sexual dysfunction, incontinence, etc.), but found that “education was the key” to changing his perspective.

“I get a lot of solace in sharing my experience with others, and (meeting) others like him. He remarked that talking to other prostate cancer sufferers and survivors has been “therapeutic”. When asked what his reaction would be if active surveillance discovers a resurgence of prostate cancer, he replied: “If I am diagnosed tomorrow with advanced prostate cancer, I still bought over a year of normalcy… I have no regrets.”

Alan currently lives in Wanaque, NJ, with his wife, and has four daughters and five grandchildren.
“This is the Genomic Era,” said George W. Sledge, Jr., MD, outgoing President, at the opening session of the American Society of Clinical Oncologists’ annual meeting held in Chicago in June. Addressing his comments to over 30,000 attendees from 121 countries, Dr. Sledge of Indiana University’s Simon Cancer Institute, said the new era of cancer treatment will use genomes (maps of genetic material in cells) to find drivers of cancer, isolate those drivers in the clinic, and find a way to stop them. In less than a decade, the science has progressed from mapping the human genome to mapping the first cancer genome. We can even get our own genetic information downloaded onto a USB drive.

As genetic details of cancer become available to researchers, it would seem finding a cure would be easier. But, as Dr. Sledge pointed out, these scientific breakthroughs will also bring complications. With each individual, there are unique patterns and mutations—each possibly requiring a unique set of therapies. He described two types of cancers: ‘stupid cancer’ and ‘smart cancer.’ Stupid cancers have a single dominant mutation that can be treated with a single therapy and resistance is rare. Smart cancers contain multiple and large mutations, need complex therapy, and show early and frequent resistance to treatment. These smart cancers will require “a magic shotgun, not a magic bullet,” he said, “with multiple drivers targeted simultaneously.” Because of the complexity of the Genomic Era in cancer, Dr. Sledge believes clinical trial design will need to be updated, data will have to be real-time and precise, and oncologists will need to become “clinical cancer biologists.”

Another theme at the annual meeting was an emphasis on biomarkers. Biomarkers are critical early warning signals of disease—for example, high blood pressure is a biomarker for vascular disease, as noted by Dean Brenner, MD. In cancer, biomarkers can be used in prevention and perfect them.

In prostate cancer, the controversy over the PSA biomarker continues and current diagnostic and treatment guidelines—such as annual screening, biopsies for PSA’s over 4.0, positive biopsies leading to radical treatment (surgery, radiation, etc.), and no testing for men over 75—were analyzed and challenged.

**Annual PSA Screening:** A much-discussed Swedish study questioned the need for annual PSA tests. H. Lilja, MD, reported on the study in which PSA results from a large group of Swedish men were studied over a 30-year period. They concluded: “PSA is highly predictive of long-term risk of prostate cancer morbidity and mortality. Close to half of all deaths could be prevented by intense surveillance of a small proportion of men with the highest PSA levels at age 44-50. For men with lower PSA, testing at age 51-55 and age 60 is sufficient to capture risk of prostate cancer metastases and death 10+ years in advance. This strategy would allow 50% of men to have only three lifetime PSA tests.”

**PSA Kinetics:** Dr. Mark Garzotto, MD, discussed using PSA kinetics (doubling time, velocity) when treating patients. “PSA kinetics are predictive,” he said, “and are more useful in treating patients with advanced disease.” But, he added, the numbers also need to be associated with any clinical changes in the patient, like anemia or pain. He advised using PSA kinetics as a guide when counseling patients.

**TREATING OLDER MEN WITH PROSTATE CANCER:**

**Screening:** William Dale, MD, PhD, reviewed current screening guidelines, such as no PSA testing for men over 75. He does not routinely test older men, but rather looks for any additional risk factors like family history and race. If either is a concern, and the patient’s life expectancy is estimated to be more than 10 years (overall health is good), he will do the test. If the results are positive, they will discuss follow-up. “Overall health is more critical for diagnosis and treatment than a man’s age alone,” he said.

Dr. Dale recommends that physicians consider three things: “possible benefits of treatment, possible harms of treatment, and the patient’s values and preferences.”

**Recurrence Disease:** Shabbir Alihbai, MD, asked whether age really matters when prostate cancer comes back. “Biochemical recurrence is most common in older men—usually many years later,” he said.

Androgen Deprivation Therapy (ADT), or hormone therapy, is effective for disease that has become systemic, especially for men with high Gleason scores or rapidly rising PSA’s. But the treatment has “significant toxicities.” He recommends that ADT “be restricted to men with no, or mild, co-morbidities (existing diseases like high blood pressure or diabetes) and a reasonable chance of five- to ten-year survival.”

**Advances in Prostate Cancer Therapies:** Gary MacVicar, MD, reviewed the recent progress made in treatments for advanced prostate cancer. “It has been an extraordinary year,” he said. Previous to 2010, the standard treatment for advanced prostate cancer was hormone therapy (docetaxel and prednisone) with the addition of zoledronic acid (Zometa), if bone metastases were present. Now physicians have new, FDA approved options, with more currently in clinical trials.
sipuleucel-T (Provenge) is a vaccine that stimulates a patient’s immune system
abiraterone acetate (Zytiga) + prednisone, blocks a protein that produces testosterone
cabazitaxel (Jevtana injection) + prednisone, inhibits tumor growth
denosumab (Xgeva) “interrupts the bone destruction cycle in patients with bone metastases”

Some scientific meetings are about research and results that will be years or decades away. ASCO clinicians work with patients on a regular basis, so their insights are current and patient-centric. Science is combined with a deep and abiding concern for their patients. That was the case again this year as an extremely important message was emphasized by more than one speaker: numbers and test results are only part of the story. Patient circumstances, support systems, and, most importantly, their desires, must be considered as well. As Drs. Garzotto and Dale mentioned above, one number—whether PSA or age—is not enough. “Cardiologists don’t use cholesterol [measurements] alone when diagnosing heart disease,” added Ian Thompson, MD. He pointed out that the PSA reading must be considered in combination with a man’s DRE, age, family history, ethnicity, etc. Anthony D’Amico, MD, agrees, “Don’t just look at a number; look at all of the factors.” In the fight against prostate cancer, we can’t afford to lose sight of the whole patient.

Prostate cancer is the 2nd greatest cause of cancer death among men, not only in the U.S., but worldwide. For the past 15 years The Prostate Net® has been active in bringing the messages of informed decision-making and patient empowerment to consumers, survivors and their families, and healthcare professionals. From our genesis we have been recognized by the Health on the Net Foundation as a credible source of information. But we are not alone in our mission of fighting this disease. Most recently we have partnered with other leading U.S. patient advocate organizations as part of the Prostate Cancer Roundtable to speak with a unified voice on behalf of patients, survivors and their caregivers to Congress in support of patient-centered treatment and research programs. We have also come together to address inaccuracies and/or reporting biases in media coverage that could negatively impact consumer issues. Within the past two years we have built alliances with major patient advocate organizations in Canada, Europe, Australia, New Zealand, Argentina, India and Africa as part of the World Wide Prostate Cancer Coalition. Our global initiatives are now expanding further with our acceptance into the United Nations ECOSOC Civil Society Network working to address the situation of non-communicable diseases in emerging countries. It has been said that “it takes a village” to make change happen. The Prostate Net is proud to be a part of this global advocacy “village” working to improve conditions for societies around the world.
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Registration for the Symposium is Free! Please indicate the location for which you are registering
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August 27 – MEN’S FELLOWSHIP BREAKFAST –
Ann Arbor, MI; University of Michigan Cancer Center □

September 10 – PROSTATE CANCER SYMPOSIUM –
Chicago, IL; Northwestern University Lurie Cancer Center □

September 17 – PROSTATE CANCER SYMPOSIUM –
Detroit, MI; Karmanos Cancer Center □

September 24 – “I’LL GO IF YOU GO” PROSTATE & BREAST CANCER EVENT –
Komen of North Jersey □

October 29 – PROSTATE CANCER SYMPOSIUM –
New York, NY; New York University Kimmel Center □

November 12 – “I’LL GO IF YOU GO” PROSTATE & BREAST CANCER EVENT –
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Maha Hussain, M.D., FACP - Professor of Medicine & Urology at the University of Michigan, and Associate Director of Clinical Research for the U-M Comprehensive Cancer Center. Her research interests include new therapies for prostate, bladder, and kidney cancers.

Isaac Powell, M.D. – Professor in the Department of Urology at Wayne State University and Karmanos Cancer Institute. His research interests include prostate cancer in African American men, community-based education, and early detection.

Derek Griffith, Ph.D. - Assistant Professor in the University of Michigan School of Public Health and Director of the Center on Men’s Health Disparities. His research interests include the role of lifestyle factors on black men’s physical and mental health.

Hosted by the University of Michigan Comprehensive Cancer Center Community Outreach Program and The Prostate Net.

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